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SY

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/236,897 01/26/99 KOMATSU

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EXAMINER

IM52/0814

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CROSS I

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/236,897

Applicant(s)

KOMATSU, AKIHIRO

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,296,069 to Smith et al (hereinafter Smith et al >069) in view of US Patent 4,053,381 to Hamblen et al (hereinafter Hamblen et al >381).

Smith et al '069 disclose an apparatus for processing analysis slides in a chemical analyzer. The apparatus comprises a meter device **18** for metering (spotting) sample fluid from sample cups on a sample tray onto an analysis slide of the colorimetric type. A second meter device is provided to deposit sample and reference fluid onto analysis slides of the potentiometer type (col. 3, lines 40-45). Incubators **22**, **24** are provided to function with analysis means **23**, **25** from measuring a change in the analysis slides as a result of the fluid being deposited thereon (col. 4, lines 40-45). Results from the analysis means **25** may be transmitted to a computer for appropriate calculations of concentration for various samples (col. 7, lines 53-58). Control circuits are provided which include thermistors for controlling the temperature of various heating elements (col. 4, lines 28-37). Also disclosed are housings **14**, **16** where analysis slides are supplied and moved between the incubator **24** and analysis means **25**, via a slide

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transfer mechanism **128**. The position of the analysis slide is detected by means of an optical sensor (col. 6, lines 33-36).

The chemical analyzer disclosed by Smith et al '069 does not contain ion-activity measuring means. However, Smith et al '069 does disclose that analyzers comprising a pair of electrodes selective to ion activity may be used (col. 3, lines 12-22). Hamblen et al '381 teach ion selective electrodes for determining ion activity in liquids. Hamblen et al '381 teach that the use of such ion-selective electrodes in chemical analysis helps to minimize errors in the readings obtained.

Thus, it would have been obvious to one of ordinary skill in the art to use ion-selective electrodes such as those disclosed by Hamblen et al '381 in the chemical analyzer apparatus of Smith et al '069 to help in obtaining more accurate readings for the analyses performed.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Smith et al '069 and Hamblen et al '381.

3. Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al '069 and Hamblen et al '381 as applied to claims 1-3 and 5-7 above, and further in view of US Patent 5,814,277 to Bell et al '277 (hereinafter Bell et al '277).

With respect to claims 4 and 8, neither Smith et al '069 nor Hamblen et al '381 disclose Applicants' claimed feature of a diluting unit where the sample is diluted with a diluent.

Bell et al '277 teach an automatic chemical analyzer comprising sample and reagent containers **22, 24**. Aliquots of sample and reagent are drawn up from the chambers and dispensed into test cells. Bell et al '277 disclose that the samples may be diluted automatically by dispensing buffer solution from reservoir 52 into the test cells. The automatic dilution of sample is disclosed as being advantageous when the sample concentration is too high or when limited amounts of sample are available for testing. Automated dilution also eliminates the potential for user error in sample dilution. See col. 9, lines 10-18.

Thus, it would have been obvious to one of ordinary skill in the art to include a dilution unit in the apparatus of Smith et al '069 to allow a greater number of assays to be performed and to reduce risk of user error in diluting the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Smith et al '069, Hamblen et al '381 and Bell et al '277.

Response to Arguments

1. Applicant's arguments filed May 23, 2001 have been fully considered but they are not persuasive. Applicants' arguments, regarding the rejection over Smith et al '069 in view of Hamblen et al 381, are directed to Applicants' assertion that the recited means for spotting are not taught or suggested by the art. Applicants seemingly contend that two "means for spotting" are not disclosed by Smith et al. In response, Smith et al '069 teaches two types of analysis slides are present in the processing apparatus –

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colorimetric type analysis slides and potentiometric type analysis slides. Colorimetric type analysis slides use color to determine the presence or concentration of a specific analyte. Potentiometric type analysis slides measure voltage (electrical potential) by comparison with a standard (reference). Smith et al '069 further teaches that the second metering (spotting) devices meters reference fluid onto slides of the potentiometric type already containing sample fluid. Applicants are incorrect in stating that Smith et al '069 teach "spotting a reference liquid onto each analysis element". Smith et al '069 clearly teach that only the potentiometric type slides are metered with the reference liquid.

Applicants further assert that improper hindsight reasoning was used in combining the teachings of Smith et al '069 with Hamblen et al '381. Indeed, such is untrue, especially since Smith et al '069 names the ion activity measuring means of Hamblen et al '381 in its disclosure. Applicants' are incorrect in stating that "Hamblen et al '381 is not concerned with measuring ionic activity of a specific ion in a sample liquid." The abstract of Hamblen clearly states "a device and method for determining ion activity in liquids". The disclosure of Hamblen motivation the skilled artisan to use such ion activity measuring means by stating that such "helps to minimize errors in readings".

Applicants further state that the limitations of claims 3 and 7 are not taught or suggested by Smith et al '069 and/or Hamblen et al '381. As pointed out in this and the previous Office Action, Smith et al '069 teaches the use of an optical sensor to detect the position of the transfer means. The skilled artisan would recognize that the since

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the transfer means carries the slides (analysis elements), the position of the slides are also being detected. Applicants' recitation of how the detecting means works is insufficient to impart patentability of the claimed apparatus. Claims directed to an apparatus must be distinguished from the prior art in terms of structure and not function. See MPEP 2114.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC *LC*
August 8, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700